

Exhibit H

Shelby F. Thames, Ph.D.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., MASTER FILE NO.
PELVIC REPAIR SYSTEM 2:12-MD-02327
PRODUCTS LIABILITY LITIGATION
MDL 2327
JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

This Document Relates To:
Margaret Stubblefield v. Ethicon, Inc., et al.
Case No. 2:12-cv-00842

DEPOSITION OF SHELBY F. THAMES, Ph.D.

Taken at Butler Snow
1020 Highland Colony Parkway, Suite 1400,
Ridgeland, Mississippi,
on Thursday, March 24, 2016,
beginning at approximately 12:29 p.m.

AMY M. KEY, RPR, CSR
Notary Public

A P P E A R A N C E S

REPRESENTING THE PLAINTIFFS:

DOUGLAS C. MONSOUR, ESQ.

KATY KROTTINGER, ESQ.

Monsour Law Firm

404 North Green Street

Longview, Texas 75601

(903) 758-5757

doug@monsourlawfirm.com

katy@monsourlawfirm.com

JACOB W. PLATTENBERGER, ESQ. (Via Telephone)

Tor Hoerman Law LLC

101 West Fulton Street

Chicago, Illinois 60661

(618) 656-4400

jake@THLawyer.com

MICHAEL H. BOWMAN, ESQ.

Wexler & Wallace LLP

55 West Monroe Street, Suite 3300

Chicago, Illinois 60603

(312) 346-2222

mhb@wexlerwallace.com

PATRICIA L. CAMPBELL, ESQ.

Potts Law Firm

1901 W. 47th Place, Suite 210

Westwood, Kansas 66205

(816) 931-1312

pcampbell@potts-law.com

REPRESENTING THE DEFENDANTS:

CHAD R. HUTCHINSON, ESQ.

Butler Snow LLP

1020 Highland Colony Parkway, Suite 1400

Ridgeland, Mississippi 39157

(601) 985-5711

chad.hutchinson@butlersnow.com

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S T I P U L A T I O N

It is hereby stipulated and agreed by
respective attorneys of record, that this
deposition may be taken at the time and place
hereinbefore set forth, by AMY M. KEY, Court
Reporter and Notary Public, pursuant to the Rules;
That the formality of reading and
signing is specifically RESERVED;
That all objections, except as to the
form of the questions and the responsiveness of
the answers, are reserved until such time as the
deposition, or any part thereof, may be used or
sought to be used in evidence.

1 (EXHIBIT NOS. 1 THROUGH 3 PRE-MARKED.)

2 SHELBY F. THAMES, Ph.D.,

3 having been first duly sworn,

4 was examined and testified as follows:

5 EXAMINATION

6 BY MR. BOWMAN:

7 Q. Good afternoon, Dr. Thames. My name is
8 Mike Bowman.

9 A. Good afternoon, sir.

10 Q. You've been handed Exhibit 1. Can you
11 tell me if you've seen that document before?

12 A. I have not seen this document before.

13 Q. Does that look like a notice of deposition
14 to you?

15 A. Oh, this Exhibit 1 here? I haven't seen
16 this, no, sir.

17 Q. Could I see it for a second?

18 A. Sure.

19 Q. So it's been pre-marked as 1.

20 Have you had a chance to look through it?

21 A. Just glanced through it, yes, sir.

22 Q. And you did not see that before?

23 A. I have not.

24 Q. Do you see the name "Margaret
25 Stubblefield" on there?

1 A. Let's see. Yes.

2 Q. Okay. I'm here representing her. You did
3 a case-specific report for her mesh; is that right?

4 A. Yes, sir, I did.

5 Q. Do you know when you finished this report?

6 A. This is Thursday. I don't remember. It
7 was one day last week, about ten days ago, so...

8 Q. I've also handed you another document,
9 Doctor, that's been labeled Exhibit 2.

10 Do you see that there?

11 A. I do.

12 Q. Have you seen that document before?

13 A. No, sir.

14 Q. Well, I represent to you that that was
15 provided to plaintiff's counsel with your expert
16 report.

17 Have you had a chance to look through it
18 at all?

19 A. No.

20 MR. HUTCHINSON: Counsel, do you have
21 another copy?

22 MR. BOWMAN: I do.

23 BY MR. BOWMAN:

24 Q. Do you know who might have prepared this
25 document, Doctor?

1 A. Are we talking about 2, sir?

2 Q. Yes, 2.

3 A. I have no idea.

4 Q. I'm going to guess by the color on the
5 front that it was prepared by somebody at Exponent
6 by the cover page.

7 Do you see that?

8 A. Yes.

9 Q. Would it make sense that somebody from
10 Exponent prepared this document?

11 A. Yes.

12 Q. Actually, if this were in color, it would
13 be a green and white cover page, which I typically
14 see when I deal with Exponent documents.

15 A. Well, that looks like their style, and
16 that's why my answer to your question.

17 Q. So do you understand that -- you
18 understand that, in this case, that Kevin Ong did
19 cleaning for you; is that right?

20 A. Yes, sir.

21 Q. Can you just take maybe two minutes or
22 three minutes to review the document, Exhibit No. 2,
23 and tell me if it looks anything like what you and
24 Kevin Ong discussed?

25 A. Okay.

1 Q. Okay. Thank you.

2 MR. HUTCHINSON: Counsel, you stated
3 that this was included with the e-mail. Are
4 you talking about this document, Exhibit No.
5 2, was produced with the Stubblefield report?

6 Is that what you're telling us?

7 MR. BOWMAN: I believe it was produced
8 as part of the Rule 26 report, so not with
9 the amended Stubblefield.

10 MR. HUTCHINSON: Okay. And it wasn't
11 produced with the original Stubblefield?

12 MR. BOWMAN: I don't think it was.

13 MR. HUTCHINSON: All right. I'm sorry.
14 I think I misunderstood you then.

15 MR. BOWMAN: Okay.

16 MS. KROTTINGER: Is that the cleaning
17 protocol?

18 MR. BOWMAN: It is, yeah.

19 MS. KROTTINGER: Yeah. That was
20 produced with each case-specific report, the
21 original one, not the amended one.

22 Does that make sense?

23 MR. BOWMAN: This is the handling
24 protocol from -- it looks like the handling
25 protocol from Exponent.

1 MS. KROTTINGER: Yes.

2 THE WITNESS: I've had a chance to
3 glance through it, sir.

4 BY MR. BOWMAN:

5 Q. Does it refresh your recollection of what
6 the document is?

7 A. I have never seen it before.

8 Q. Do you know what the document is after
9 having looked through it?

10 A. Well, it is a recommended protocol for
11 cleaning. And I think the second sentence, 1.2,
12 says what it is actually. It's to evaluate the
13 effects of different cleaning methods on clean
14 surface texture and chemistry of the mesh material.

15 Q. Okay. So this --

16 A. Under 1.2.

17 Q. So you don't believe that this is in any
18 way representative of the protocol that was used?

19 A. For what?

20 Q. To clean the meshes in the case?

21 A. My meshes?

22 Q. No, the mesh for Ms. Stubblefield.

23 A. No, sir.

24 Q. Okay. This is just the protocol that the
25 lab used whenever they would handle a mesh; is that

1 right?

2 A. No, sir. This is not -- they didn't
3 handle our meshes this way.

4 Q. Okay.

5 A. Our meshes were handled precisely the way
6 they are in this cleaning report here.

7 Q. Okay.

8 A. We never used dimethylsulfoxide or nitric
9 acid or any of these chemicals they're talking
10 about.

11 This is a method -- the way I perceive
12 this document is that they're taking this to
13 evaluate the effects of different cleaning methods
14 on clean surface textures and chemistry of mesh
15 material.

16 Q. Okay.

17 A. So I don't know that they set this up as a
18 cleaning protocol. It's a trial cleaning protocol,
19 the way I evaluate the document.

20 Q. Okay. So one way or another, you haven't
21 seen it before, and you don't know if it's been
22 utilized in the Stubblefield case at all?

23 A. It has not been.

24 Q. Now, a minute ago you referenced the
25 Stubblefield report. You actually referenced the

1 protocol that's in the amended Stubblefield report?

2 A. That is correct.

3 Q. And, as I understood it, there was an
4 outdated protocol that was part of the original
5 Stubblefield report; is that correct?

6 A. Well, no, sir. What happened is in the
7 process of putting the document together, the
8 original protocol that we used for cleaning implants
9 was placed into the Stubblefield report
10 inadvertently, and not the more current one where we
11 have reduced the time. We talked about that
12 earlier.

13 The time of -- for instance, the first
14 step was distilled water and heating at 70 degrees
15 at 20 hours. In the original report, it was heated
16 for 42 hours. And rather than drying by room
17 temperature, it was dried under desiccation. So
18 it's minor changes, but that's the case.

19 Q. And what's in the amended report
20 represents your understanding of what was done by
21 Mr. Ong; is that right?

22 A. Absolutely.

23 Q. As I understand it, he would do a
24 cleaning. He would send it to you, and then you
25 would send it back to him for cleaning; is that

1 right?

2 A. Yes, sir.

3 Q. What was done when it came back to you?

4 Do you know?

5 A. When we received it, we did light
6 microscopy, scanning electron microscopy and Fourier
7 transform infrared spectroscopy analysis of the
8 sample. And then we, of course, recorded that data.
9 We sent it back to him. He does the next cleaning
10 step. He sends it back to us. We repeat those
11 three analyses and send it back to him, and that's
12 done for five cleaning steps.

13 Q. So the five cleaning steps, is that
14 independent to Ms. Stubblefield's case, or was that
15 done in every case?

16 A. Every case.

17 Q. So why did you do it five times?

18 A. Well, our protocol was set up for five
19 times -- excuse me. There's a case where we didn't
20 do five. There's one case where we stopped after
21 the second cleaning step, I believe. I don't
22 remember the name. But it was because the explant
23 itself was so clean there wasn't any need to go any
24 farther. And we noticed that by SEM and by FTIR and
25 light microscopy as well.

1 Q. So the samples come to you. You make a
2 determination on whether or not they go back; is
3 that right?

4 A. We typically will send them back, yes,
5 sir.

6 Q. But the determination is made by you
7 whether or not they get sent back?

8 A. Myself and Dr. Ong, we talk about
9 together.

10 Q. And the maximum number of times that you
11 sent this -- that you would send a sample through
12 the cleaning protocol is five?

13 A. Five.

14 Q. Why did you choose five as a maximum
15 number?

16 A. Well, we set this out originally to be our
17 cleaning protocol. You were here earlier this
18 morning when we testified why each step was done. I
19 could go through that again if you would like for me
20 to.

21 But we did that in order. And after each
22 cleaning step, we evaluated the explant to make
23 certain we weren't damaging it. We also wanted to
24 get it as clean as we could, so we do it through
25 five steps. In some cases, it hasn't taken that

1 much. But we went through five steps, irrespective
2 of one sample.

3 Q. One sample for the Wave 1 case that you
4 examined?

5 A. Yeah, that's right.

6 Q. Do you remember the name?

7 A. No.

8 Q. Can you tell me very quickly or even in a
9 more detailed explanation what you mean when you say
10 the sample was examined by light microscopy?

11 A. When the sample comes to us, we take it
12 out and we put it under a light microscopy. We
13 examine is pretty thoroughly and take
14 photomicrographs of it. I'm going to -- it's best
15 for me to answer this by referring to this report,
16 which is Exhibit 3.

17 Q. Okay.

18 A. Is that okay my doing that?

19 Q. Yes, that's fine.

20 A. I'm looking on page 3. So on page 3,
21 we've got a Gynemesh exemplar sample. And we always
22 do an exemplar. Before cleaning -- and that you
23 notice it says 20 times magnification in this bar.

24 So that's the kind of material that we're
25 looking at. And, as you notice, it says figure 2 is

1 pristine kind of mesh, and that's before cleaning.

2 And then we look down at the sample. The
3 Stubblefield sample is figure 3, label 1.3.1.

4 That's before cleaning.

5 And so then we go from there, and we go
6 take a photomicrograph of that on page 4 of the
7 exhibit and figure 4. And we do that to see if --
8 during that process, we look to see if there are any
9 fibers that may be sticking out from the mass of the
10 implant and try to look for something that they
11 would show us before we start the cleaning process.

12 There wasn't a whole lot here that was
13 beyond the confines of the fatty mass that we found.
14 But what was there is the type photomicrograph that
15 was in figure 4.

16 Q. So sticking with the first light
17 microscopy image, image 2, and that's on page 3,
18 that's Gynemesh, correct?

19 A. Yeah.

20 Q. And you say it's labeled as pristine
21 Gynemesh, GPSL, Lot K -- I'm sorry -- Lot CKB435
22 before cleaning?

23 A. Yes, sir.

24 Q. How many of these Gynemesh did you examine
25 for the plaintiff-specific reports, if you know?

1 A. I don't know.

2 Q. So I'll be more specific. There are two
3 general types of mesh at use in Ethicon's pelvic
4 mesh products, correct?

5 A. There are several.

6 MR. HUTCHINSON: Object to form.

7 BY MR. BOWMAN:

8 Q. So there's SUI meshes and POP meshes,
9 correct?

10 A. Yes.

11 Q. That are pure polypropylene?

12 MR. HUTCHINSON: Object to form,
13 Counsel.

14 THE WITNESS: No, that's wrong. They're
15 not pure polypropylene. None of the meshes
16 that are used by Ethicon are pure
17 polypropylene. They're all Prolene.

18 BY MR. BOWMAN:

19 Q. They're all Prolene?

20 A. And they all have additives, five of them,
21 as a matter of fact. And we need to make that
22 really clear here.

23 Q. I understand. The differentiation that I
24 was making is that there is a Prolift+M, which is
25 half polypropylene --

1 A. I'm sorry. You're speaking a little fast
2 for me.

3 Q. Sure. There is Prolift+M that is made out
4 of the ULTRAPRO mesh, and we're not talking about
5 that in this case.

6 A. That's right.

7 Q. But what I'm trying to understand is
8 that -- I want you to -- I don't know how many POP
9 meshes you've examined for the plaintiff-specific
10 reports. But I'm trying to figure out how many
11 times you ran Gynemesh through -- this Gynemesh
12 sample through the cleaning process, or did you have
13 a different sample?

14 A. No, no. We ran it through the cleaning
15 process at every point of the cleaning stage. We
16 went through the 25 steps of the cleaning process,
17 just like explant did. And we evaluated it at the
18 end of every cleaning by light microscopy, FTIR,
19 just like we evaluated this one.

20 Q. So did you do a new pristine Gynemesh
21 sample for every case-specific report that had
22 Gynemesh involved?

23 A. I'm not sure. I would have to refer back
24 to what was used here.

25 Q. Well, the way I read this is --

1 A. Because we've got a sample -- when we
2 received a sample from Dr. Ong, he sent us an
3 exemplar which he used. He chose the appropriate
4 one for her case. And so I think they're the same,
5 from the same lot number, but I cannot testify
6 specifically to that without looking at the
7 documents.

8 Q. So did he -- do you know if Dr. Ong ran a
9 new piece of pristine Gynemesh with every POP
10 product that he looked at?

11 A. Yes.

12 Q. He did?

13 A. Yes.

14 Q. So this photograph in figure 2 is going to
15 be different for another POP-specific case that you
16 did -- I'm sorry -- for another POP case that you
17 did a case-specific report on; is that right?

18 A. That's true.

19 MR. HUTCHINSON: Just so we're clear,
20 POP, pelvic organ prolapse.

21 BY MR. BOWMAN:

22 Q. So I just wanted to make sure that we
23 weren't working with -- I just wanted to make sure I
24 understood what the report said.

25 A. Well, there were really -- if he runs it

1 through one time and photographs it and documents
2 it, there really would be no need to run it through
3 five, six, seven, eight times, but that's what's
4 here.

5 Q. Right. But he didn't run the same piece
6 of mesh through the protocol more than five times?

7 A. The same piece?

8 Q. Right.

9 A. No.

10 Q. Do you know how big this piece of mesh is
11 before it was magnified.

12 A. Well, no. You can see the legend that
13 shows the millimeters. It's not real big, but it's
14 not as small as a lot of our explants. There's no
15 need to have a large size, quite honestly.

16 Q. Did you handle these meshes as they came
17 to you?

18 A. No, I did not handle them. My technical
19 guy that works for me handles them. I saw them. I
20 looked at them, but I didn't handle them. He takes
21 care of that. He does the cleaning process -- or
22 excuse me. He didn't clean them. He does the
23 process of doing SEM, the optical microscopy and the
24 FTIR. He's my technical assistant.

25 Q. Just so I can understand the protocol, the

1 untested sample from Steelgate or Roberson or
2 wherever the mesh came from, it would come to your
3 office. You would document it with FTIR and light
4 microscopy?

5 A. It would come from Dr. Kevin Ong. He
6 would get the sample, take it to Exponent, do the
7 first step of the process. Actually, he would do --
8 let's see what steps we've got here. He would do
9 the first two steps. After that, he would send it
10 to me.

11 Q. So he did the first two steps, and then he
12 would send it to you?

13 A. And we would then do light microscopy,
14 FTIR, and scanning electron microscopy. We would
15 send it back to him, and then he would do the third,
16 the fourth and the fifth step and send it to me. We
17 would do the sixth step, light microscopy, FTIR and
18 scanning electron microscopy and send it back to
19 him. He would do seven, step eight, nine, ten
20 and -- nine through ten, and then he would send it
21 back on the 11th step. That's how it progressed.

22 Q. So what was the purpose of actually
23 sending the explant to your office?

24 A. We wanted to determine the progress of
25 cleaning at each step rather than waiting until we

1 went through five steps and then here's the explant.
2 We wanted to see the progress that was being made to
3 clean the explant because we were identifying it at
4 each step and running the scanning scopes, the FTIR
5 and the optical photomicrographs so that we could
6 get a feel for how it was being cleaned.

7 Q. And you saved all that data, and it's been
8 produced to the plaintiffs; is that right?

9 A. Yes, sir.

10 Q. Do you know is all that data reproduced in
11 this report?

12 A. Not in this report. I can't get all that
13 data in this report.

14 Q. So I think -- well, I'll get to it later,
15 but I think there are multiple FTIRs there.

16 A. Oh, there are some, yes. Wait a minute.
17 We took more FTI- -- we took more scanning electron
18 photomicrographs than we put in this report just for
19 the volume of size. We selected some representative
20 ones, but all that information has been provided to
21 you.

22 Q. Okay. So the photos in this report don't
23 necessarily represent the entire --

24 A. The totality.

25 Q. -- the totality of the mesh that you

1 examined; is that right?

2 A. Of the samples that we ran, right. That's
3 correct.

4 Q. What about the data points? So all the
5 FTIR is not on here. The SEMs and the light
6 microscopy, they do not represent the totality of
7 the images that you captured; is that right?

8 MR. HUTCHINSON: Object to form.

9 THE WITNESS: Whatever we did more than
10 once, you have a copy of it.

11 BY MR. BOWMAN:

12 Q. But it's not in the report?

13 A. Some of -- no, sir, just because we didn't
14 want the report to be so voluminous, so big.

15 MR. HUTCHINSON: Counsel, just for the
16 record, we have e-mailed that information to
17 you. We did that when?

18 MS. KROTTINGER: Tuesday.

19 MR. HUTCHINSON: Tuesday of this week.

20 MR. BOWMAN: Okay.

21 MR. HUTCHINSON: So we e-mailed all
22 SEMs, all light microscopy and all FTIRs,
23 everything that was done.

24 THE WITNESS: Everything that's done you
25 have a copy of.

1 MR. BOWMAN: Okay.

2 BY MR. BOWMAN:

3 Q. Now, with respect to Ms. Stubblefield's
4 mesh, on page 4, --

5 A. Yes, sir.

6 Q. -- you say that there's a higher
7 magnification of 200 times?

8 A. Yes, sir.

9 Q. It says that it shows the fiber as encased
10 within a dry and cracked proteinaceous layer?

11 A. Yes, sir.

12 Q. And that's represented in figures 4 and 5?

13 A. 4 and 5, yes, sir.

14 Q. Could you show me on 4 what you mean by
15 the proteinaceous layer? Is that this --

16 A. This is a colored picture. It's this
17 darker layer here. This is protein, fat, so forth,
18 and here is the fiber. And 5 shows that right here.
19 And then the other picture is after we -- it says
20 this is Stubblefield after cleaning one. That's the
21 fiber. So we took this and we cleaned it through
22 the first step, and we got that.

23 Q. Okay. The first one, figure 4, is that
24 200 times magnification, and figure 5 is --

25 A. 200 magnification.

1 Q. But it's just a different portion of the
2 mesh that you took a picture of?

3 A. That's right.

4 Q. Now, with respect to the -- sorry. Did
5 you have more to say?

6 A. No.

7 Q. With respect to light microscopy, could
8 you explain a little bit more about the process that
9 you used to take the photos using light microscopy?

10 A. Well, you take the sample with a pair of
11 tweezers very gently and you put it under the light
12 microscopy lens, and you get a focus on it. You
13 select the magnification, and you move it around
14 very gently. And you try to get things in focus
15 that would tell the story you wanted to tell, i.e.,
16 is there any damage here and what does it look like.
17 What does the surface look like?

18 And when you can get something in focus
19 and it looks like it's important, you snap a picture
20 of it, and that's recorded. Part of that picture is
21 recorded, and then it's sent back to whomever. And,
22 from there, we print this picture out and put it in
23 the report.

24 Q. So with respect to the photos 4 and 5,
25 there's a background. What is the background? It

1 appears to be black.

2 A. Yes.

3 Q. What is that?

4 A. Typically, they use a carbon stub or a
5 black piece of paper or a black background, yes,
6 sir.

7 Q. Do you know -- so are the samples that you
8 took with these photos, are they in solution, or are
9 they just in room -- I'm sorry -- are they in
10 ambient air, or what are they in?

11 A. They're in air.

12 Q. And that's just --

13 A. They're dry at this point in time. You
14 know, he has cleaned them and dried them and sent
15 them to us. So when we get them, they're dry.

16 Q. But you don't use any sort of enhancement
17 techniques, say, putting them in fluid or any kind
18 of oxygen-rich environment or nitrogen-rich
19 environment. It's just straight room ambient air,
20 and it gets put underneath a microscope and you snap
21 a picture?

22 A. Yes, sir. And that's the way it is for
23 all of our samples we evaluated for the FTIR and the
24 SEM.

25 Q. With respect to the outermost layer -- and

1 I'm looking at figure 5 right now --

2 A. All right, sir.

3 Q. -- of Ms. Stubblefield's report.

4 A. Uh-huh (affirmative response).

5 Q. I see a lot of, I would say, transverse
6 lines.

7 A. Can you see color on your computer?

8 Q. I can, yes.

9 A. Okay. Good.

10 Q. I can see color on my computer, and I know
11 you don't have color in front of you. Because the
12 report was produced a couple of days ago or maybe a
13 day ago, I didn't have a chance to get to a color
14 printer. So I'm working off my laptop, and you're
15 working off --

16 A. I just wanted to make sure you could see
17 it, because it tells you so much more than in black
18 and white.

19 Q. Yes, I'm sure it does. So with respect to
20 the way photo 5 is taken, the light is coming down
21 from the microscope itself; is that right?

22 A. Yes, sir.

23 Q. Or is there another source of light inside
24 the --

25 A. No, it's coming from the microscope

1 itself. And, also, we can adjust the light from the
2 side to get a good -- so that we see the picture
3 appropriately. So you've got light coming from the
4 microscope, and you can adjust it from the side. I
5 don't take the pictures. My technician does.

6 Q. So how familiar are you with light
7 microscopy?

8 A. Well, just enough to use it. I don't take
9 it -- I don't use it a lot.

10 But what do you mean by the question?
11 I've used it for years.

12 Q. Sure. So what I meant by the question is
13 that the way you just described it is that there's a
14 light source coming directly out of the sample and
15 then from the side, correct, or it can be from the
16 side?

17 A. Or it can be at any angle. You can move
18 it around so that you can get a better view, a
19 better vision of what it is that you want to take a
20 picture of.

21 Q. And if we look at the blue portion, the
22 direct center of figure 5, you can actually see it
23 pretty much all around the sample, but I'm going to
24 stick to the center just for the sake of clarity.

25 There are what appear to be horizontal

1 cracks running along or horizontal lines. Let's
2 just call them "lines" for the sake of this
3 photograph.

4 A. They're 90-degree angles to the fiber.

5 Q. That's a good way of describing it. Now,
6 how is it you ruled out the -- I'm sorry. Strike
7 that, please.

8 Did you take into account any kind of
9 refractive index associated with polypropylene?

10 A. Not for the light microscopy, we did not.

11 Q. So with respect to the surface of this
12 sample, how is it that the outer layer appears to
13 have -- how is it that we have the magnification of
14 the outer layer so that we can see these cracks?

15 Did you do anything to enhance that at
16 all?

17 A. Just focus the microscope.

18 Q. So this is exactly how it looked under the
19 microscope?

20 A. Absolutely.

21 Q. If you had taken the refractive index of
22 polypropylene into account, would that have had any
23 effect on the photograph itself?

24 A. Not for the light microscopy. If you're
25 talking about polarization of lights, then this --

1 polypropylene is birefringent, so that would come
2 into play, but not here.

3 Q. And you didn't do any of that kind of
4 testing for this specific report?

5 A. I have not for this report.

6 Q. Have you done it in the past?

7 A. Rarely. We find what we need by using
8 light microscopy and scanning electron microscopy.
9 It tells a story, along with FTIR.

10 Q. Okay. Now, you go on to talk about the
11 chemical structure analysis by FTIR, microscopy.
12 But I wanted to stick with this photograph, because
13 I know that you made reference in the report to
14 flakes not being blue.

15 So could you explain to me what you mean
16 by that?

17 A. If you will look over here, I'll try to
18 point this out.

19 THE WITNESS: Can I use your pen? Thank
20 you, Chad.

21 BY MR. BOWMAN:

22 Q. That will be an exhibit. So if you mark
23 it, it will go --

24 A. Do you want me to mark it? I can mark it?

25 Q. Yes, absolutely.

1 A. If you'll notice, I've drawn a circle
2 around -- I'm going to put "clear." And then you'll
3 see these areas right in here, "blue." And if
4 you'll notice, they're cracked lines at 90-degree
5 angles to the direction of the fiber.

6 And it's particularly interesting to look
7 at the one I've marked "clear." You'll notice how
8 the proteins have actually lost their adhesion to
9 the fiber and are lifted up almost like this
10 (indicating), like I'm doing my hand here. They
11 were adhered, and now they're lifted up. And you
12 can see that very clearly right here, and you can
13 see the same thing here, but it's a little bit
14 different angle.

15 The reason we know that these are both
16 proteins is because we've done FTIR spectra of
17 these. And if this particular explant -- and all of
18 these, by the way -- and I found this in every one
19 of the case-specific explants we looked at.

20 If this happened to be Prolene, then this
21 would be blue, not translucent. This is translucent
22 here. And you'll see underneath it, it looks a
23 little different. That's pure -- that's the explant
24 right here that I'm pointing to at the bottom of the
25 clear mark on this exhibit.

1 So we've got translucent materials coming
2 off of the clear fiber. We've got clear translucent
3 material coming off the blue fiber. If this were
4 Prolene flaking, it would be blue, and it's not.

5 So that photograph and others that I've
6 taken show that this is not -- we are not seeing
7 Prolene on the surface -- excuse me. We're not
8 seeing proteins flaking from the -- let me back up.

9 We are seeing the fiber with a protein
10 layer losing adhesion and physically rising from the
11 explant in the form of a crack, and we see that both
12 for the blue fiber and the clear fiber.

13 Point being, if it was Prolene cracking,
14 the blue material we see rising up from Prolene
15 would be blue. It would be the same color as
16 Prolene, and it is not. It's translucent, just like
17 the clear material from the clear fiber is
18 translucent.

19 Q. So have you done any experiments to
20 determine how thick a piece of bark or peeling off
21 material would need to be to show color?

22 A. Well -- excuse me.

23 MR. HUTCHINSON: Object to form.

24 THE WITNESS: I think any piece would
25 contain some particles of blue dye.

1 BY MR. BOWMAN:

2 Q. So we're talking about -- how thick do you
3 think that this piece of outer layer is on this
4 Prolene here that you've pointed out and circled
5 there?

6 A. We have not measured that on that specific
7 piece of fiber, but we've measured some similar to
8 that before, and they're around 3 microns.

9 Q. So, just for reference, this had Gynemesh,
10 and it would -- would you agree with me that the
11 monofilaments used here are 3.5 mil?

12 MR. HUTCHINSON: Object to form.

13 THE WITNESS: I haven't measured them,
14 but I think that's -- I don't believe that's
15 accurate. I would think they would be
16 thicker than that, but I didn't measure the
17 thickness of the Gynemesh itself.

18 BY MR. BOWMAN:

19 Q. Do you know how thick the Gynemesh is
20 supposed to be on the monofilament level?

21 A. I haven't looked at that.

22 Q. Do you know how thick the TVT is supposed
23 to be on the monofilament level?

24 A. TVT, we measured those, and they're around
25 175 microns.

1 Q. You're dealing with microns. I know it
2 as -- let me see if I can refresh your memory this
3 way.

4 From reading the documents, I've read that
5 the TVT is made out of monofilaments that are as
6 thick as -- they're supposed to be as thick as
7 6 mil. And my understanding is --

8 A. That's 25.4 microns per mil. So that's
9 about 150, 160, so that's 6 mils.

10 Q. And my understanding is that -- when we're
11 saying six mils, is that 6/100 of an inch or --

12 A. 6/1,000 of an inch.

13 Q. Thank you.

14 So 6/100 of an inch would be an order of
15 magnitude larger than what it actually is for TVT;
16 is that right?

17 MR. HUTCHINSON: Object to form.

18 THE WITNESS: 6/100?

19 BY MR. BOWMAN:

20 Q. I'll withdraw the question.

21 In any event, with the Gynemesh, what
22 we're actually looking at is we're looking at a
23 very, very small amount of material that's peeling
24 off.

25 And, frankly, on the exhibit that you have

1 there, --

2 A. Yes, sir.

3 Q. -- I actually -- if you could turn it my
4 way, I'll point it out to you, because we are
5 dealing with this diagram.

6 What I see here is I see a piece that is
7 folded off, and then directly beneath it is a very
8 strong blue color. And I see here a piece that is
9 peeled off that actually appears to be clear.

10 Would you agree with those two statements,
11 or what do you think?

12 MR. HUTCHINSON: Object to form.

13 THE WITNESS: Let me have your marker.

14 Well, yes, that does look like blue beneath
15 that. So I might have mislabeled that,
16 because it might be a blue fiber. Let me
17 check and see.

18 It is blue. My mistake. This should be
19 changed to blue, because this translucent
20 protein is coming up above this blue fiber
21 here. And when I first glanced at it, I
22 thought it was clear, but it's not. It's blue.

23 Can I have your pen? I'm going to mark
24 through it, and this is on page 5 of Exhibit 3,
25 and I'm going to change "clear" to "blue."

1 So this fiber is blue, and is this
2 translucent material here is rising up from
3 that fiber, which actually makes my point.

4 If this is polypropylene, it would be
5 blue. It wouldn't be translucent. And we see
6 that in all these explants. You're exactly
7 right. It's blue.

8 BY MR. BOWMAN:

9 Q. So you understand my confusion, Doctor,
10 because it looks like the blue fiber is actually
11 part of the weave, and it also looks like the clear
12 fiber is part of the weave there as well. So I
13 don't understand that photo. You first identified
14 it as clear, and now you've identified it as blue.

15 To me, it looks like the clear is coming
16 off of a white fiber because it's paired with that
17 other white fiber there.

18 Do you see that?

19 MR. HUTCHINSON: Object to form.

20 THE WITNESS: Yes, I do.

21 BY MR. BOWMAN:

22 Q. Then there is the blue fiber coming
23 through. So I don't understand this picture.

24 MR. HUTCHINSON: Is there a question
25 pending, Counsel? Because what I heard was,

1 "I don't understand this picture."

2 BY MR. BOWMAN:

3 Q. So can you explain to me why you changed
4 your identification of that one as clear to now
5 blue?

6 A. Sure. When I first looked at this, I saw
7 the -- this is in a knotted area, a weave area that
8 we're looking at. And when I first saw the area
9 that I've changed and marked with a pen as clear, I
10 didn't focus clearly enough on what was underneath
11 the lifted portion of the proteins there. And it's
12 blue underneath, not clear. And that was the
13 mistake that I made and just didn't notice that.
14 And then I did mark the blue area, which is blue.

15 But adjacent and on the left of the blue
16 area, which I have changed from clear to blue, is a
17 clear fiber, which also shows, below where the pen
18 mark is, the proteins, how they are raising
19 themselves up from the clear fiber, just as they did
20 with the blue, and the part of the protein that is
21 lifted and has lost adhesion and is beginning to
22 flake off is translucent on the clear fiber just
23 exactly like it's translucent on the blue fiber.

24 My point is this: If the materials that
25 are coming off of the clear fiber were Prolene, they

1 would expect to be clear because the Prolene fiber
2 was clear. If the material that's lifted up and is
3 translucent and coming off the blue fiber, if it was
4 Prolene, it would also be blue, and it is not blue.
5 So, therefore, that material cannot be Prolene.

6 Q. Can you explain to me what your
7 understanding is of how Prolene gets its blue color?

8 A. Yes. There is a phthalocyanine blue
9 pigment added to it during the process of it.

10 Q. And that's the same time when the
11 antioxidant's added; is that right?

12 A. That is correct.

13 Q. Now, that pigment obviously isn't added to
14 the white portion, correct?

15 A. No. That is correct.

16 Q. So there are clear pellets of -- there are
17 clear pellets of Prolene, and there are blue pellets
18 of Prolene out there; is that right?

19 A. Yes, sir.

20 Q. And the extrusion of both, you wouldn't
21 mix the two of them, would you?

22 A. Not with an extruder, no.

23 Q. Because then the color would be decreased?
24 That would probably be the only difference between
25 the two if they were both Prolene pellets, correct?

1 A. That's correct.

2 Q. So with respect to the blue pigment, I'm
3 still trying to understand how it is you came to the
4 conclusion that something so thin peeling off would
5 show off as blue, which I actually don't see in
6 these pictures, but how you came to the conclusion
7 that using this technique you would be able to see
8 blue in a piece of bark coming off of the Prolene
9 suture?

10 MR. HUTCHINSON: Object to form.

11 THE WITNESS: When the fibers are made,
12 the blue pigment -- it's not a dye. It's a
13 pigment. It's added, and the blue pigment is
14 dispersed throughout the entire piece of blue
15 fiber. The outer portion of the blue fiber
16 cannot be excluded having blue pigments,
17 because it's one mass of material.

18 So when it's extruded from the extruder,
19 blue pigment particles are throughout. When
20 it's put in the body, it's blue pigment
21 particles throughout.

22 Therefore, if there is oxidation of blue
23 Prolene pigments -- or blue Prolene fiber, you
24 will see that oxidation product being blue and
25 not translucent.

1 BY MR. BOWMAN:

2 Q. But in answer to my question, you haven't
3 done any research to confirm that?

4 A. That's research. What you're looking at
5 is research.

6 Q. So what you circled originally as clear
7 and then you changed to blue is the research?

8 MR. HUTCHINSON: Object to form.

9 THE WITNESS: Well, it's research in the
10 sense that we were looking to see what -- we
11 had an explant here that we were trying to
12 evaluate and determine what happened to that
13 explant during the time it was in
14 Ms. Stubblefield. And we've used a very --
15 basically, we just cleaned it with water
16 here. And we've looked at it again, a little
17 sodium hypochlorite, and here we see these
18 fibrous materials coming off of the white and
19 the blue pigment -- or fibers. Excuse me.

20 BY MR. BOWMAN:

21 Q. Isn't it just as likely that the material
22 that's flaking off is actually reflecting light into
23 this medium?

24 A. No.

25 Q. Why not?

1 A. It's too obvious here. If you look at
2 this -- and this is just one photomicrograph. We've
3 got others. It is very clear that this is not just
4 light -- I'm not sure what you said.

5 Q. Reflecting.

6 A. Reflecting, no. Otherwise, the entire
7 issue would be light reflecting, and that's not the
8 case.

9 Q. Why isn't it?

10 A. It's just not. That's not the way
11 microscopy works.

12 Q. Honestly, I still can't find anywhere here
13 with a blue piece that is flaking off. I do see
14 that there are blue outlines that seem to have, you
15 know, some sort of pattern associated with them,
16 especially at the turns. There are breaks there.

17 Do you see those?

18 MR. HUTCHINSON: Wait a minute. Object
19 to form. Compound question.

20 What's the question pending, Counsel? I'm
21 sorry.

22 BY MR. BOWMAN:

23 Q. The question I asked is, did you see the
24 breaks and the turns of the blue suture through the
25 mesh?

1 A. I don't see any breaks in the suture at
2 all.

3 Q. Can I show you? So there are horizontal
4 cracks here, here, here and here.

5 Do you see those?

6 MR. HUTCHINSON: Object to form.

7 THE WITNESS: Yes. Those are cracks,
8 and that's protein cracking. That is not the
9 fiber.

10 BY MR. BOWMAN:

11 Q. So the protein is -- it's a clear material
12 that will still show us blue underneath?

13 MR. HUTCHINSON: Object to form.

14 THE WITNESS: Let me see if I can show
15 you what I'm talking about. If I take a
16 piece of paper, a thin piece of paper, and,
17 all of a sudden, I take the thin piece of
18 paper and lay it on top of another piece of
19 paper and the two dislodge from each other,
20 one loses adhesions and one raises up, if
21 it's translucent, I can see through it into a
22 blue fiber, but it will be translucent. And
23 that's what we're seeing here.

24 BY MR. BOWMAN:

25 Q. So that actually brings me back to my

1 question earlier, which is, why isn't light
2 reflecting through oxidized polypropylene?

3 Why isn't that just as possible as the
4 idea that it's protein?

5 MR. HUTCHINSON: Objection. It's been
6 asked and answered.

7 THE WITNESS: You're asking me if you
8 take a colored photograph of something,
9 everything should be the same color. That's
10 basically your question to me, and that's not
11 the way it works.

12 BY MR. BOWMAN:

13 Q. I was actually using the example that you
14 just used to explain why there wasn't this outer
15 layer on the mesh itself that you could see through.

16 If light is passing through, then why
17 isn't light also bouncing back?

18 MR. HUTCHINSON: Objection. Form.

19 THE WITNESS: I'm trying to explain to
20 you why the allegations that have been made
21 are that what we see here is oxidized
22 polypropylene. And you have a wonderful
23 example here of the fact that if it's
24 oxidized polypropylene and it's losing its
25 adhesion to propylene, then it would be blue

1 just like propylene is blue, and it is not.

2 So, therefore, it is not propylene.

3 BY MR. BOWMAN:

4 Q. I don't think you answered my question,
5 Doctor. What I'm trying to get at is I'm trying to
6 find the basis of your conclusion here that, number
7 one, and I'll stick to the -- I'll go in parts.

8 The first thing I want to know is why you
9 think that the flaked-off layers would -- you would
10 be able to see a blue hue in them?

11 A. Why?

12 Q. Yes. Why?

13 A. Because they're blue. They should have
14 the pigment in them. And if they have pigment
15 particles in them, just like the rest of the
16 Prolene, they would be blue.

17 Q. Irrespective of the --

18 MR. HUTCHINSON: I'm sorry. Dr. Thames,
19 go on and finish your answer.

20 THE WITNESS: And since they are not
21 blue, it means that they are not Prolene.

22 BY MR. BOWMAN:

23 Q. Now, it's interesting you keep saying
24 that, because everything in this photo looks kind of
25 blue to me, and I think it's because of the black

1 backdrop and because of the fact that there is
2 clear/blue here.

3 So the idea that something isn't blue, I'd
4 really like you to point it out.

5 MR. HUTCHINSON: Objection. Counsel,
6 that's also argumentative. You're asking
7 this witness to interpret what you see in
8 this photograph, which clearly cannot be
9 done.

10 MR. BOWMAN: Well, the photograph will
11 be shown to the jury. That's for sure.

12 MR. HUTCHINSON: Good. So please
13 reformulate your question, please.

14 BY MR. BOWMAN:

15 Q. The question is, how is it that you can
16 say that the flaked-off material in the two
17 positions that you've indicated in Exhibit 3 do not
18 have blue associated with them?

19 MR. HUTCHINSON: Objection. That's been
20 asked and answered. Last time.

21 THE WITNESS: I'm marking another area,
22 and I'm going to call it "clear." And here
23 is the flake from the clear Prolene sample,
24 no pigment in it, and you see that it is
25 clear.

1 When you look -- if you look right here,
2 you see blue, blue right there. But this flake
3 is translucent. And this is a translucent
4 covering over this blue fiber, and that flake
5 is lifted up above that fiber. The flake is
6 not blue.

7 MR. MONSOUR: I don't mean to interrupt.
8 Can I ask you a question, though, since
9 you're pointing this out?

10 You're talking about this piece right here
11 that's kind of sticking off right there?

12 THE WITNESS: No, sir. I'm talking
13 about this piece right here. You see, this
14 is the clear fiber and it's under the --
15 where I said blue at the very top, I marked
16 through clear and put blue. There's blue
17 where my pen is located right here.

18 MR. MONSOUR: Yeah, I see that's blue.

19 THE WITNESS: And then directly above it
20 is translucent.

21 MR. MONSOUR: It is?

22 THE WITNESS: And you see this entire
23 sheath that's covering this fiber is
24 translucent? This is a blue fiber, and this
25 sheath around it is translucent.

1 MR. MONSOUR: So what you're saying is
2 this is a blue fiber, and there is white
3 stuff or translucent stuff on top of it?

4 THE WITNESS: And that's proteins.

5 MR. MONSOUR: What's this?

6 THE WITNESS: This is a clear fiber
7 where it's flaking too, and that's protein as
8 well, and it's clear. Clear fiber should be
9 clear. This should be blue if this is
10 Prolene, and it's not.

11 MR. MONSOUR: Okay. I think I see. I
12 was totally lost. Sorry, Mike.

13 MR. BOWMAN: That's fine.

14 BY MR. BOWMAN:

15 Q. So I think we've established that you
16 found -- you found what you've identified on this
17 Exhibit 3 as being two blue portions that have clear
18 flakes and a clear portion that has clear flakes; is
19 that right, Doctor?

20 MR. HUTCHINSON: Object to form.

21 THE WITNESS: You're going to have to
22 restate that and slow down.

23 BY MR. BOWMAN:

24 Q. On the picture that you have in front of
25 you, you have identified two portions of blue suture

1 that have clear flakes; is that right?

2 A. Yes, translucent flakes.

3 Q. And then you have identified one portion
4 from a clear suture that has a translucent flake; is
5 that right?

6 A. Yes, sir, correct.

7 Q. So that was the first part of what I'm
8 asking you.

9 The second part of what I'm asking you is,
10 do you have anything to back up the fact that --
11 what you've just found?

12 MR. HUTCHINSON: Objection. Asked and
13 answered.

14 THE WITNESS: I think I have described
15 it as efficiently as I am capable of
16 describing it.

17 BY MR. BOWMAN:

18 Q. But you don't have any research to back it
19 up?

20 MR. HUTCHINSON: Objection. That's been
21 asked and answered. He's already told you
22 he's done research on it.

23 THE WITNESS: What is your definition of
24 "research"?

25 BY MR. BOWMAN:

1 Q. Something in a peer review.

2 A. Peer review?

3 Q. Yes.

4 A. Sir, we do research to put stuff in the
5 peer review. Not everything that's researched is in
6 the peer review.

7 Q. I understand that. But you don't have
8 anything in a peer review to support what you're
9 stating in this report for Ms. Stubblefield; is that
10 right?

11 MR. HUTCHINSON: Object to form.

12 THE WITNESS: Peer review? This will go
13 in the literature to be peer reviewed. But,
14 no, this is my finding, and I think it's very
15 clear and that most anyone will be able to
16 understand it. Because not only do we find
17 this here, we find it in 19 other cases just
18 like this.

19 BY MR. BOWMAN:

20 Q. Okay. So with respect to -- getting back
21 to the report, it says -- on the second paragraph,
22 it says, "FTIR analysis of the flaked and peeling
23 material from both clear and blue fibers are
24 consistent and further confirms the cracked and
25 peeling materials are proteins, not Prolene."

1 Do you see that?

2 A. Yes, I do.

3 Q. Where are those FTIRs?

4 A. My FTIR analysis starts on page 5 -- 6,
5 excuse me, of this report. And if you'll notice in
6 the top left, it says, "Stubblefield 1.3.1, before
7 cleaning clear fiber FTIR or micro." That's before
8 any cleaning has been done.

9 And then this is the FTIR spectra. And
10 you'll notice that what we see here is that we see
11 the peaks that are characteristic of polypropylene
12 or, in this case, Prolene that are marked in blue.
13 And then you see peaks down here that say, "Protein
14 amide carbonyl stretching." It's marked, so that's
15 protein here. And you see, "Protein N-H stretch,"
16 over to the left around 3300.

17 So this FTIR shows you that we are seeing
18 proteins and Prolene.

19 Q. Okay.

20 A. All right. And it shows you where the
21 picture was taken, the photomicrograph was taken, in
22 the top right-hand corner.

23 Q. So this -- but if we look at the top
24 right-hand corner, I don't see a flaked or peeling
25 portion there, do you?

1 A. We're not necessarily looking for a flaked
2 or peeling portion there, sir.

3 Q. Okay. So that was my question, because
4 that's what the paragraph says here back on page 5.
5 It says, "FTIR analysis of the flaked and peeling
6 material" --

7 MR. HUTCHINSON: Counsel, can you slow
8 down for me?

9 MR. BOWMAN: Sure.

10 BY MR. BOWMAN:

11 Q. Do you see it on page 5?

12 A. Yes.

13 Q. So it says that FTIR was done on flaked
14 and peeling material, doesn't it?

15 A. I'm going to read this for you.

16 Q. Okay.

17 A. It's the before cleaning fiber FTIR
18 spectra, figure 6, which is the one I'm referring
19 to, shows spectral components of both polypropylene
20 and proteins as noted by the highlighted 3291 and
21 1651 reciprocal centimeter frequencies respectively.
22 These adsorption frequencies are attributed to the
23 protein amide N-H stretching in the 3300 centimeter
24 region and the amide 1 carbonyl stretching in the
25 region of 16 to 1690 reciprocal centimeter region as

1 noted by Kong, et al., respectively.

2 Polypropylene adsorption frequencies are
3 also present at 1449 and 1378 reciprocal centimeters
4 due to penetration of the IR beam through the
5 protein layer and into the polypropylene fiber.

6 That's what it says, nothing like what you
7 asked me.

8 Q. Thank you for reading from the report,
9 Doctor.

10 The second paragraph on page 5, it states
11 that, "FTIR analysis of the flaked and peeling
12 material from both clear and blue fibers are
13 consistent and further confirms the cracked and
14 peeling materials are proteins, not Prolene."

15 Where are those FTIRs?

16 A. Okay. Let's look at them. On page 7,
17 figure 7, Stubblefield, this is photomicrograph of
18 tissue taken between the fibers. In other words,
19 you've got fibers laying out here, and we took a
20 photomicrograph between the fibers, not in the area
21 of the fibers. And it was overlaid with a
22 collagenase, which is a protein reference spectra
23 that comes from a library.

24 And you'll notice that the blue is the
25 spectra from the tissue. The red is from the

1 control collagenase. You'll notice that every peak
2 in the fiber -- the FTIR between fibers as there is
3 in collagenase. So we show protein. Okay?

4 Q. Yes.

5 A. Are you okay with that?

6 Q. Respectfully, that wasn't the question I
7 asked.

8 A. I'm going to answer your question.

9 Q. All right.

10 A. And you also see a blue spectra that's not
11 in the collagenase. It's at 1742.

12 Q. Yes, I see that.

13 A. We'll get to that.

14 Q. Okay.

15 A. If you go to the next spectra, which is
16 figure 8, this is the -- if you look at the top
17 left-hand corner, Stubblefield 1.3.1, before
18 cleaning tissue between fibers FTIR micro. And then
19 it's compared to before cleaning the blue tissue
20 FTIR micro.

21 So you see both the blue and the -- before
22 cleaning tissue between FTIR micro, blue tissue.
23 Okay. This is before cleaning the blue tissue.
24 This is the peak of the blue tissue micro.

25 You'll see that the blue tissue has the

1 same materials on it as the blue fiber with the FTIR
2 micro. So we've got blue and clear tissue here
3 that's got the same FTIR spectra.

4 Now, let's go to the next one.

5 Q. Before we keep going, because I only have
6 a certain amount of time, I want to just withdraw my
7 question, and I need to ask a much more specific
8 question.

9 A. All right.

10 Q. Did you take any of the peeling and flaked
11 material and run FTIR on it?

12 A. You mean take it with a pair of tweezers?

13 Q. Yes, sir.

14 A. You couldn't do that. It's too small.

15 Q. So why does that statement there on page 5
16 that says you did the analysis of the flaked and
17 peeling material, why is that there if you didn't do
18 it?

19 A. Because I looked at those flaked --

20 MR. HUTCHINSON: Object to form. The
21 witness has told you he did do it.

22 MR. BOWMAN: Actually, he didn't tell me
23 he did it.

24 THE WITNESS: Well, I did it by looking
25 on the implant. You can see where it is, and

1 we showed proteins are there. We showed that
2 they're there. And then we kept cleaning,
3 and, finally, the proteins are gone.

4 And you're dismissing the part of the
5 cleaning process completely when you stay on
6 one photomicrograph. This is -- we go from
7 before cleaning through 25 steps, and you can
8 see progressively how these proteins are lost.
9 And you can look at -- if you really want to
10 know the real truth, go to page 9.

11 BY MR. BOWMAN:

12 Q. Doctor, I'm going to ask you to stop
13 answering. Because, like I said, I only have so
14 much time, and I do have questions about the rest of
15 the report.

16 A. Okay.

17 Q. Now, with respect to what's on page 5,
18 there is figure 5, and it says after cleaning 1.
19 And you've already marked it in Exhibit 3 as you saw
20 at least three places where there was flaked
21 material.

22 A. At least.

23 Q. For the record, did you ever run FTIR on
24 the flaked material that you see in Exhibit 3 --

25 A. Yes, we did.

1 Q. -- on page 5?

2 A. We did that when we took this sample, and
3 we found a sample where there was flaked material,
4 and we did the FTIR analysis of that.

5 Q. You picked it up with tweezers?

6 A. No, we did not. We did the FTIR analysis.
7 And what I was trying to get at over here is it
8 showed both proteins -- those spectra showed both
9 proteins and the Prolene fiber.

10 And as we cleaned it, the protein peaks
11 went away. To begin with, you saw both proteins and
12 Prolene. In the next spectra, you would see less
13 proteins and then Prolene.

14 So, therefore, the fact is simple that,
15 well, it was protein because they were cleaned off
16 and were left of a blue fiber, and that's what
17 page 5 tells us.

18 Q. Okay. Continuing on page 5, it says, "The
19 presence of a thin remaining translucent protein
20 layer on a Prolene fiber after flesh had been
21 mechanically removed proves a strong protein
22 adsorption and a strong adhesive bond formation
23 between the adsorbed proteins and Prolene."

24 Do you see that?

25 A. Yes, sir.

1 Q. And that's consistent with what you
2 testified about within your general deposition with
3 respect to the use of formaldehyde or formalin; is
4 that right?

5 A. Yes, sir, but not only formalin and
6 formaldehyde. I said proteins themselves have a
7 strong adhesive bond, if you'll remember that part.

8 Q. I do remember. Thank you.

9 A. Okay.

10 Q. Going to the next paragraph, the before
11 cleaning fiber FTIR spectra, do you see that?

12 A. I do.

13 Q. You point out that, figure 6, "spectral
14 components of both polypropylene and proteins as
15 highlighted by bands at 3291 and 1651."

16 Do you see that?

17 A. Yes, I do.

18 Q. What are you looking for in those bands?

19 A. I want to show that when we look at these
20 cleaned fibers, that the first cleaning steps, the
21 FTIR spectra shows your proteins are there and
22 Prolene is there. And as we clean, as we go through
23 this cleaning process that I've talked about all
24 morning long, as you go from step one, step two,
25 step three, step four, step five, more and more

1 proteins are cleaned off. And, finally, you look at
2 a FTIR spectra and you're seeing only Prolene, and
3 that's shown on page 9.

4 Q. Okay. And I get the progression of your
5 report, Doctor, and I appreciate --

6 A. And the spectra shows protein and Prolene,
7 protein and Prolene.

8 Q. I get the progression of your report,
9 Doctor, and I also understand that the progression
10 of the report was done at your direction, correct?

11 A. Yes, sir.

12 Q. So if you saw proteins on FTIR, then you
13 sent it back for more cleaning; is that right?

14 A. Correct.

15 Q. Now, with respect to Ms. Stubblefield on
16 Exhibit 6, we are looking at the before cleaning
17 FTIR.

18 Do you see that, figure 6, on page 6?

19 A. You said Exhibit 6.

20 Q. I'm sorry. It's Exhibit 3 still.

21 A. Figure 6?

22 Q. Yes.

23 A. Yes.

24 Q. Now, you point out the protein amide 1
25 carbonyl stretch?

1 A. Yes, sir.

2 Q. And you state that that is at 16; is that
3 right?

4 A. Yes, sir.

5 Q. And that's a broad peak, right, on the
6 FTIR?

7 A. Yes, sir, it is.

8 Q. With respect to the protein amide nitrogen
9 hydrogen stretching that you point out at 3290, is
10 that a broad peak?

11 A. Yes, it is.

12 Q. With respect to -- do you see any hydroxyl
13 groups showing up in this FTIR?

14 A. I don't think you can distinguish a
15 hydroxyl group here. It's too broad in the 33-,
16 32-, 3100 range.

17 Q. Well, let's start there.

18 Where would a hydroxyl group show up?

19 A. In the same general area as the NHP would
20 show up. There is a fairly -- you can see that the
21 resolution is not as good there as it is over in the
22 frequency range right at 1700.

23 Q. So there could be hydroxyl groups there or
24 no?

25 A. There could be, but I don't think they're

1 shown in this curve, because there may be a very
2 small amount that's overridden or oversaturated by
3 other things that are there.

4 Q. And could that be the amide group?

5 A. It could be.

6 Q. Now, with respect to the protocol used on
7 Ms. Stubblefield's mesh, what was done to protect
8 the possibility that hydroxyl groups were there?

9 A. What hydroxyl groups?

10 Q. On the surface of her mesh.

11 A. From what?

12 Q. Oxidized polypropylene?

13 A. No. You're going to get carbonyl groups
14 first. You're going to get the C=O bonds, which are
15 going to show at the 1700 range.

16 Q. So my question is --

17 A. And much more easier to define.

18 Q. So my question is, what was done to
19 protect the presence of hydroxyl groups on
20 Ms. Stubblefield's mesh?

21 A. Okay. Very good question.

22 Very mild cleaning conditions as we've set
23 up here in this protocol.

24 Q. Okay. Very mild cleaning conditions.

25 Did you at any point run oxidized

1 polypropylene through your protocol?

2 A. No, sir, I have not.

3 Q. Do you know what would happen if you ran
4 purposefully oxidized polypropylene through your
5 protocol?

6 A. Yes, sir, I think I do.

7 Q. And what would happen?

8 A. You would have the same thing at the end
9 that you started with at the beginning, just like an
10 exemplar.

11 Q. And you're speaking about polypropylene
12 with carbonyls; is that correct?

13 A. I'm speaking about Prolene. When we
14 talk -- see, I'm not talking about polypropylene.

15 Q. I keep mixing that up.

16 A. I'm here today to talk to you about
17 Prolene, P-R-O-L-E-N-E.

18 Q. Which is Ethicon's priority blend of --

19 A. And the answers that I've inadvertently
20 given you when you asked about polypropylene, I was
21 making the assumption, which is wrong, that you were
22 talking about Prolene.

23 Q. I've been speaking specifically about
24 Ms. Stubblefield's case, so we've been talking about
25 Prolene all day.

1 A. Okay.

2 Q. Now, with -- I just wanted to -- you know,
3 I wanted to find out if any steps had been taken to
4 protect the possibility that carboxyl groups were on
5 her mesh.

6 Did you understand that question?

7 A. I did. I answered it, too.

8 Q. And you did answer it.

9 With respect to the peak that shows up at
10 1740, --

11 A. Yes, sir.

12 Q. -- what would -- what does that tell you,
13 that peak at 1740?

14 A. That tells me -- I received two or three
15 implants that were dry, that were not in
16 formaldehyde. And those particular samples had the
17 same frequency as we're looking here at 1740. And
18 that's due to decomposition of the flesh. And
19 that's referenced by Notter and Stuart. It's very
20 clear. There's a very fine article on that.

21 And so, in my opinion, somewhere along the
22 way, this explant was left out long enough for
23 decomposition to begin.

24 Q. With respect to 1740, that's a peak at
25 1740, correct?

1 A. It is.

2 Q. And I believe earlier today you testified
3 that a peak at 1740 is indicative of a carbonyl
4 group; is that right?

5 A. Yes, it is.

6 Q. Now, what was done with respect to
7 Ms. Stubblefield's mesh to protect the possibility
8 that she had oxidized polypropylene on her mesh with
9 respect to the carbonyl that's there?

10 A. We took Ms. Stubblefield's explant, and we
11 put it through the cleaning protocol that I know
12 you're familiar with, because you've been here all
13 morning and we've talked about it. And that's a
14 very mild cleaning protocol, and it was developed
15 for its mildness because it would not cause any
16 undue reactions with the polypropylene -- or the
17 Prolene mesh and, therefore, would not change it
18 from its original shape or form or composition when
19 it came out of the patient.

20 Q. And I understand that. But my question
21 was specific to oxidized polypropylene -- I'm sorry.
22 My question was specific to oxidized Prolene that
23 came out of that -- that might have come out of
24 Ms. Stubblefield.

25 What steps were taken to prevent oxidized

1 Prolene with reacting with your protocol?

2 MR. HUTCHINSON: Object to form.

3 THE WITNESS: I just answered your
4 question. That's the answer to your
5 question.

6 BY MR. BOWMAN:

7 Q. The answer that you gave me was that it
8 would stay in the same way that it was when it came
9 out of the patient.

10 A. Well, isn't that protecting whatever was
11 there?

12 You asked me a question, how do I go about
13 protecting the explant from changing whatever was
14 there? And you used hydroxyl, which I don't think
15 happens. So I'm going to say whatever might have
16 been there such that when we finally looked at it,
17 it was in the same shape, form and composition, and
18 that's why this mild cleaning protocol was set up,
19 and that's why we did it that way. And there was no
20 oxidation going on.

21 Q. But isn't the -- you've already testified
22 that your protocol was used five times with respect
23 to Ms. Stubblefield and that it was at your
24 direction when it was sent back for each cleaning
25 process, correct?

1 A. And at no time did we see anything in the
2 interim between those steps that's reported here in
3 this cleaning process where we did light microscopy,
4 FTIR or SEM did we see anything that suggested that
5 there was any oxidation there. All of the spectra
6 are here, and that's why we've included it in here,
7 all of those spectra.

8 Q. So with respect to the FTIR that we're
9 looking at, I've already given you two ranges, one
10 where a hydroxyl group would be and one where a
11 carbonyl is.

12 Did you run a control where you had a
13 piece of Prolene that had a hydroxyl group on it or
14 had a carbonyl on it and run it through your
15 protocol to make sure that your protocol did not
16 destroy that oxidized Prolene?

17 A. I ran an exemplar of Prolene and found
18 that nothing changed on its surface during this
19 period of time, which means that, therefore, if
20 there was something on the explant, it would still
21 be there when I finally got through step five, that
22 I would not have removed it, and it would still be
23 there.

24 Q. I tend to agree with the answer you've
25 given --

1 A. Well, good.

2 Q. -- if we assume that no oxidized
3 polypropylene is on the explant.

4 What did you do to protect any oxidized
5 Prolene that might have been on Ms. Stubblefield's
6 mesh?

7 MR. HUTCHINSON: Object to form. That's
8 been asked and answered, Counsel, several
9 times. You just don't like the answer this
10 expert is giving you. So last time, and then
11 I'm instructing the witness not to answer.

12 MR. BOWMAN: I'm trying to find out if
13 he destroyed evidence. That's all I'm doing
14 here.

15 MR. HUTCHINSON: Well, you've asked the
16 question three times, and you don't like the
17 answer. So my point is --

18 MR. BOWMAN: Technically, I'm not
19 getting an answer. Every answer I'm getting
20 is it would be the same. I've tested it on
21 Prolene. I'm not asking him about Prolene.
22 I'm asking him about oxidized Prolene.

23 BY MR. BOWMAN:

24 Q. Doctor, I would be more --

25 MR. HUTCHINSON: I understand that. But

1 that's my objection, and that's going to be
2 my instruction. So this is the last time,
3 Counsel. I just want to make sure we all
4 understand.

5 BY MR. BOWMAN:

6 Q. Do you need me to re-ask the question?

7 A. I do, and then I need for my attorney to
8 tell me whether I need to answer it again, because I
9 have answered it three times, but go ahead.

10 Q. This before cleaning FTIR has two bands,
11 has an area that could show a carboxyl group and an
12 area that could show a carbonyl group that could
13 both be associated with oxidized Prolene; is that
14 right?

15 A. When you say "could," you're making an
16 assumption that if they were there, that would be
17 where they would be located. That is probably a
18 reasonable assumption, but they're not there is what
19 I'm trying to tell you, because I've taken it
20 through five steps, and I've identified it with
21 FTIR, five steps. They're not there. It wasn't
22 there.

23 Q. Well, this is the before cleaning.

24 A. Yes, it is.

25 Q. So we can go to the next one now. That

1 would be fine. If we went to Exhibit 7, --

2 A. Sure.

3 Q. -- I'm sorry -- figure 7. Now, figure 7
4 actually shows -- that's the tissue before fibers,
5 correct?

6 A. This is the tissue between fibers.

7 Q. Between fibers. And it's overlaid with
8 collagenase reference, and we've already talked
9 about that.

10 A. And what I wanted to show you, now, listen
11 carefully --

12 Q. I do have a question coming, and I think
13 you know what it is.

14 MR. HUTCHINSON: Perfect, but the
15 witness is going to finish his answer. So,
16 Dr. Thames, you finish your answer.

17 MR. BOWMAN: Well, he's already given me
18 the explanation for this figure.

19 MR. HUTCHINSON: I'm telling you,
20 Counsel, right now that the witness is going
21 to finish his answer.

22 So, Dr. Thames, finish your answer.

23 THE WITNESS: You asked about this. And
24 the 1742 peak -- this is to show you that the
25 1742 peak is present in tissue between the

1 fibers and it's not associated with the
2 fiber. So, therefore, it cannot be DLTDP.

3 MR. MONSOUR: Would you repeat that?

4 THE WITNESS: Yes, I will. If you
5 assume there's a mesh and you've got strands
6 of mesh and then between that you've got
7 tissue, well, we took an FTIR of that tissue,
8 not on the fiber, but that tissue. And this
9 is the spectra you see here in blue. It says
10 between the fibers. It clearly shows the
11 1740 peak.

12 MR. MONSOUR: Where you say "between the
13 fibers," is that --

14 THE WITNESS: It's right here, blue, the
15 tissue between fibers.

16 MR. MONSOUR: Okay.

17 THE WITNESS: And it shows you the 1740
18 peak. That wasn't taken in an area where
19 there was a fiber. You go to the reference
20 Notter and Stuart, and they will show you
21 this spectra at 1740 for decomposed flesh.

22 BY MR. BOWMAN:

23 Q. I understand your answer, Doctor. Thank
24 you.

25 MR. HUTCHINSON: Why don't we take a

1 quick break?

2 (A BREAK WAS TAKEN.)

3 MR. BOWMAN: Back on the record.

4 BY MR. BOWMAN:

5 Q. Doctor, Exhibit 3, page 7, figure 7.

6 A. Yes, sir.

7 Q. Just so I have some clarity, figure 7 is a
8 before cleaning tissue between fibers FTIR, and that
9 is in blue and then some collagenase?

10 A. That's a reference spectra, yes.

11 Q. It's a reference spectra, and that's in
12 red?

13 A. Yes, sir.

14 Q. And I believe before we took a break you
15 indicated that the FTIR for the tissue, there was no
16 chance that there were fibers in there?

17 A. That's correct.

18 Q. Were you there when the FTIR was taken?

19 A. No, sir.

20 Q. But your assistant was, and he -- do we
21 have a picture of that FTIR?

22 A. Sure. It's somewhere. We've shown it
23 several times.

24 Q. So I saw the -- so on page 6, upper
25 right-hand corner of that figure, there is sort of

1 like a target of where that was taken?

2 A. He just didn't do that here. I don't know
3 why. I gather it was because it was between the
4 tissues. But the point -- we talked about this.
5 And I said, "Look, we need to make certain that this
6 is not in the area of the fibers, the Prolene," and
7 we did -- he did, and that's the spectra that was
8 accrued from it.

9 Q. Okay. Figure 8, there is a -- it
10 indicates that in blue there is a before cleaning
11 tissue between fibers.

12 Do you see that?

13 A. I do.

14 Q. And it indicates that in red there was a
15 before cleaning blue fiber?

16 A. Uh-huh (affirmative response).

17 Q. And it says "FTIR micro."

18 What does "FTIR micro" mean?

19 A. Well, it's done with an FTIR spectrometer,
20 but it's a microscope where you can zero-in on a
21 very small portion.

22 Q. And do you know which portion they
23 zeroed-in on for this?

24 A. I guess the blue fiber. And the red, it
25 doesn't -- he looked at the fiber and made certain

1 that he was on a fiber, and the blue spectra he made
2 certain that he was between the fibers. And that's
3 the two spectra.

4 Q. So you're saying that -- so because there
5 wasn't a photo taken, we have no way of knowing what
6 portion of the blue fiber was analyzed for this?

7 A. No, sir.

8 Q. No, sir, there isn't any way to find out
9 or --

10 A. If he didn't put it on here, he didn't
11 take a picture of it. But I will ask him, if you'll
12 make a note. But I'm pretty sure that will not be
13 the case.

14 Q. So, again, these are two before cleaning
15 shots, correct?

16 A. Yes, sir.

17 Q. And then we go to image 9 -- I'm sorry --
18 figure 9.

19 A. Yes, sir.

20 Q. And it is all of the cleaning steps in
21 different colors?

22 A. For the blue fiber.

23 Q. For the blue fiber; is that right?

24 A. Yes, sir.

25 Q. Now, was a single FTIR run after each

1 cleaning step?

2 A. Yes, sir, this is it. There are five of
3 them.

4 Q. So the reason why I ask the question is
5 because sometimes I see FTIRs, and they are run with
6 20 or 30, and then the best line is plotted. That
7 didn't happen in this case?

8 A. No, sir.

9 Q. Sometimes I see them with a thousand and
10 then the best line is plotted. That didn't happen
11 in this case?

12 A. Well, it did happen in the sense that we
13 have an FTIR machine that does do something like
14 multiple of 62 scans, and then the computer brings
15 it down to the most likely spectra. So it's highly
16 efficient FTIR.

17 Q. As part of your protocol for taking FTIR
18 analysis, was the protocol to find the same point on
19 the blue fiber?

20 A. As best you could, but you can't depend on
21 that.

22 Q. So am I to understand that even though we
23 have the five cleaning -- the five FTIRs taken after
24 the five cleanings for the blue fiber, each one of
25 these FTIRs could be representative of a different

1 portion of the mesh; is that right?

2 A. It's possible.

3 (Interruption due to speaker phone.)

4 BY MR. BOWMAN:

5 Q. So I'm going to reask my question, if
6 that's all right, Doctor.

7 With respect to figure 9, we do not know
8 if the same area on the blue fiber was run at every
9 interval?

10 A. That is correct, sir.

11 Q. And we just know that it was run on blue
12 fiber?

13 A. That is correct.

14 Q. Why did you choose to check blue fiber
15 instead of -- why did you separate out blue fiber
16 from clear fiber?

17 A. Well, clear fiber is the next spectra down
18 here.

19 Q. Well, that's my question. Why did you
20 separate them? Why did you make a distinction
21 between blue and clear?

22 A. Why could you not make a distinction
23 between them?

24 My point is, what we want to do is see if
25 the blue fiber was clean and if the clear fiber was

1 clean, both of them.

2 So the logical thing to do is take the
3 blue fiber and carry it through the cleaning
4 protocol and see each step, each FTIR, and say,
5 okay, it was clean. Now, let's see if the same
6 thing happened to the clear fiber.

7 The way you're talking, I would have blue
8 and clear spectra mixed up with each other.

9 Q. That's really my question, which is
10 that -- and I do want to take -- I want to take it
11 back one step.

12 You had your assistant separate the blue
13 fiber from the clear fiber and then run FTIR on
14 them?

15 A. Yes, sir.

16 Q. So he chose or did you choose which fiber
17 to undo?

18 A. Well, you don't necessarily have to undo
19 them. You can take a sample of fiber that's still
20 in the weave net and run an FTIR on it.

21 Q. That's my understanding as well. I guess
22 my question is, what I'm hearing you say is that it
23 was separated out?

24 A. No. What was separated was that the blue
25 fiber spectra was run, and then the clear fiber

1 spectra was run. And that's separating them in the
2 sense that I want to get individual spectra from
3 each of these two fibers at each cleaning stage.

4 Q. But the mesh was only cleaned five times,
5 and the fibers weren't separated from the mesh?

6 A. In some cases, they were because they fell
7 apart. But you're asking about this specific
8 instance.

9 Q. I am.

10 A. And I don't know the answer to that.

11 Q. How can we find out?

12 A. Ask him. I can ask him. He would not
13 have done that intentionally, unless it just
14 happened during the course of getting this thing
15 five times. You see what I'm saying? They cleaned
16 it, sent it back, and then we sent it back. But he
17 would not have intentionally separated fibers.

18 Q. I understand.

19 But you did want FTIRs run separately?

20 A. Yes, I did.

21 Q. Okay. With respect to figure 9, can you
22 tell me what you see, why you've highlighted in blue
23 on the left-hand of the scan?

24 A. Yes, sir. What we were highlighting is to
25 show the peaks at 3291.

1 Do you see at the top of that?

2 Q. I do.

3 A. Okay. That's 3300. That's a little N-H
4 peak there. And you want to see the proteins that
5 were there. And, also, you'll see the 1742 peak,
6 and that comes from the decomposition products that
7 we've talked about.

8 And so what we really want to see is the
9 proteins to go away as we clean it. And as you go
10 down, then you'll see there is no peak at -- protein
11 peak available at -- when you get down to like
12 three, four and five. This is very efficient. It
13 didn't take very many steps to clean this explant,
14 quite honestly.

15 Q. And with respect to the area between 3600
16 and, let's say, 3000, do you see any area in there
17 that might be indicative of a hydroxyl group?

18 A. No, not that I can define as one, no, sir.

19 Q. Not in any of the colors after any of
20 these cleanings?

21 A. Not that I can find one, no, sir.

22 Q. With respect to the area that you've
23 highlighted in the right of the scan, can you tell
24 me why you highlighted it on the right of the scan?

25 A. Well, that's 1742. It shows that peak of

1 decomposition that I wanted to show you. It's
2 unique. Only the explants that had the
3 decomposition shows there.

4 Q. And I understand that that's what you told
5 me previously. But didn't the -- isn't the FTIR
6 from the tissue only? Isn't that a little different
7 than the peak here?

8 A. Well, we've got -- let's go back and look
9 at the FTIR. We've got tissue and explants.

10 On figure 7, we have a before cleaning
11 tissue between fibers. Then on figure 8, we have a
12 between fibers before cleaning. Let's see. We have
13 the clear fiber before cleaning on figure 6, and you
14 see the 1740 peak there.

15 Q. So looking at figure 6, 1740 is there and
16 so is 1650; is that right?

17 A. Yes, sir, that's proteins.

18 Q. Is there a peak at 1650?

19 A. Yes, sir.

20 Q. Is that peak in any way indicative of
21 carbonyl?

22 A. Yes, sir, from proteins.

23 Q. From proteins.

24 Now, with respect to the peak that is at
25 1740 in 6, is that indicative of carbonyl?

1 A. 1740, yes, sir.

2 Q. If we look at figure 9, that doesn't
3 look -- the original Stubblefield -- the before
4 cleaning for blue fiber looks a lot different than
5 figure 6 does, doesn't it?

6 A. Wait a minute. Figure six?

7 Q. Yeah. We were just looking at figure 6.

8 A. It's hard to see. It doesn't look a lot
9 different. What I'm looking at here on paper is in
10 gold, and it may be a little bit more prominent on
11 your computer.

12 But, no, sir, it doesn't look a whole lot
13 of difference at all. It's just the intensity of --
14 the resolution of the spectra here on page 8 is a
15 little bit better than on page 6.

16 Q. I was actually asking you to compare 6 to
17 9. But we can look on the same page. You don't
18 need to go to 6 for that because they're both there,
19 because 6 is of clear fiber as well.

20 So the difference between the reading that
21 we got on the clear fiber for 9, the peaks are still
22 there, right? There is just much more of them?

23 A. Yeah, and that's because you've got so
24 much flesh there.

25 Q. On the blue fiber?

1 A. Well, on both of them. You've got
2 tremendous -- we're referring back to figure 6.
3 You've got a tremendous amount of flesh there that
4 hasn't had anything done to it, so... And you still
5 get those peaks in figures 9 and 10.

6 Q. Right. I think that figure 8 and 9 -- oh,
7 9 and 10 are the two I'm looking at.

8 A. Figures 9 and 10.

9 Q. Yes. So the peaks are still there. And,
10 actually, the blue fiber -- I'm sorry. The clear
11 fiber in figure 10 is -- the before cleaning
12 actually is representative of what's in figure 6?

13 A. Yes, sir. And you see how those peaks go
14 away, the protein peaks go away as we clean it?

15 Q. I do see that. Now, with respect to the
16 fact that the blue fiber has higher peaks on it
17 than -- higher peaks at the 1650, 1660 range, do you
18 see that, between figure 9 and figure 10?

19 A. Which peak are you looking to, sir?

20 Q. 1650, 1660, right around there.

21 A. Yes. That could be -- you know, it's very
22 difficult. This is a qualitative technique here.
23 Don't misunderstand this for being quantitative.
24 It's qualitative. So the fact that it's there, in
25 order for it to be the same height, it would've had

1 to have been in the same concentration. It's not
2 necessarily in the same concentration because it's
3 not quantitative.

4 Q. Does that have anything to do with -- but
5 both of these peaks, the 1740 area and the 1650 area
6 on both the clear and the blue, these are the areas
7 where you would expect to find carbonyls; is that
8 right?

9 A. That's correct. And that's where you
10 would also expect to find oxidation if there was
11 any.

12 Q. That's right. So oxidation if there was
13 any.

14 And if we look at the first -- the
15 difference between the first and the second -- I'm
16 sorry. Let me strike that.

17 Can you think of any reason why, just
18 considering oxidation alone, why the blue fiber
19 would have a much higher peak around the 1660, 1650
20 area than why the clear fiber would have -- I need
21 to strike that.

22 Can you think of a reason why the carbonyl
23 peaks in the blue fiber are higher than the carbonyl
24 peaks in the clear fiber?

25 A. Sure. As I said, this is a qualitative

1 technique and not a quantitative technique. And in
2 order for the fibers to have exactly the same peak
3 heights, there would've had to have been two areas
4 where the amount of protein was exactly the same in
5 the blue as the clear. And the likelihood of
6 finding that is remote.

7 Q. The amount of tissue between the two; is
8 that right? Is that what you were saying? I'm
9 sorry.

10 A. Well, I don't think you're listening to
11 me.

12 Q. Okay. I'm trying to.

13 A. I'm trying to be pretty clear. Please
14 listen to me.

15 Q. I'm listening.

16 A. FTIR is a qualitative technique. You're
17 asking me to compare two spectra, one on one fiber
18 and one on a completely different fiber. And you're
19 asking me why the peak heights at a particular
20 frequency is not the same. And I'm telling you that
21 in order to be the same, the concentration at the
22 two different -- in the two different figures would
23 have to be the same.

24 Well, since this is a qualitative
25 technique and we reach over and take a fiber and we

1 run an FTIR on it, we can't say, well, the
2 concentration of the protein at this site in
3 figure 9 is exactly the same concentration of the
4 protein over in figure 10.

5 But the fact that they both occur at that
6 frequency says that protein is still there. And
7 that's what we're interested in telling you. Is
8 protein still there? And the answer is "yes."

9 Q. Did you take into account that copper is
10 used in the blue pigment when you came to that
11 determination?

12 A. That's over in seven -- like, if you look
13 over here at the blue fiber spectra, do you see it
14 over here, this peak, this red in the 700-region
15 that's not marked?

16 Q. Yes.

17 A. And you look down at the clear fiber and
18 it's not there, that says this is blue and this is
19 clear.

20 Q. I meant with respect to the blue fiber.

21 Does the addition of copper to the blue
22 fiber, does that accelerate any kind of oxidation
23 reaction at all?

24 A. Oh, no, no.

25 Q. So did you take that into account when you

1 made that determination here that there wasn't any
2 oxidation on this sample?

3 A. Well, I took it into account in the sense
4 that I would see no reason under the sun or any
5 knowledge that I have why a pigment, the
6 phthalocyanine pigment we're talking about here,
7 would have any adverse effect in terms of oxidation
8 on anything, particularly these fibers.

9 Q. Even if it was copper-based?

10 A. Yes.

11 Q. So with respect to the FTIRs that you
12 performed and with the cleaning process, you're
13 satisfied that the samples that you examined for
14 Ms. Stubblefield contained no oxidized Prolene; is
15 that right?

16 A. That is correct.

17 Q. How many different sample sites did you
18 take of the mesh that she had for FTIR?

19 A. I can't give you the exact number.

20 Q. I think we already established --

21 A. I think every site would be different.
22 You just can't identify -- when you're doing an FTIR
23 micro-spectra, you can't identify where that
24 particular site is and be assured that you're going
25 to go back to that exact site after you've taken

1 that explant and sent it to Philadelphia and they've
2 done their thing and sent it back to you.

3 Q. With respect to your conclusions about SEM
4 analysis, Doctor, --

5 A. SEM analysis?

6 Q. Yes. There were some conclusions on
7 page 11.

8 A. Okay.

9 Q. Are you with me?

10 A. I am, sir. But the SEMs are actually on
11 page 12.

12 Q. They are. The conclusions begin there,
13 and then they go to the next. So can you tell me --
14 well, I'm just going to read it into the record.

15 Your report at the top of page 12 states,
16 "If the surface of the Prolene fibers had degraded
17 as postulated by plaintiff's expert, the extrusion
18 lines would degrade during this process and would no
19 longer be visible. That is not the case we
20 observed."

21 Do you see that?

22 A. Yeah.

23 Q. Can you tell me any support for that
24 statement that you might have?

25 A. That's my belief.

1 Q. Okay. Have you reviewed any explants from
2 plaintiffs' experts while you came up with this
3 belief?

4 A. Well, every explant that I have reviewed
5 and looked at the way we've done today, first of
6 all, I've never seen oxidation; and, secondly, I've
7 always seen pristine extrusion lines, which would be
8 expected with no oxidation.

9 If oxidation had occurred, you would have
10 at least seen pitting or something, a disfigurement,
11 and I haven't seen that.

12 Q. You didn't see that in any of the pictures
13 that you took of Ms. Stubblefield's mesh; is that
14 right?

15 A. No, sir.

16 MR. BOWMAN: I think I'm done with
17 Ms. Stubblefield.

18 THE WITNESS: Okay, sir.

19 MR. HUTCHINSON: Dr. Thames, I have some
20 follow-up questions for you.

21 EXAMINATION

22 BY MR. HUTCHINSON:

23 Q. If you don't mind, if you'll look at
24 Exhibit 2, please.

25 A. Yes, sir.

1 Q. You were asked questions about a document
2 that Exponent created entitled, "Protocol for
3 Cleaning Surgical Meshes."

4 Do you recall that?

5 A. Yes, I do.

6 Q. Dr. Thames, have you had a chance to look
7 at this document now?

8 A. Briefly, yes, sir.

9 Q. And is the purpose of this protocol to
10 provide general guidance in the cleaning process for
11 those who worked at Exponent?

12 A. That's what it says to me. It says, "To
13 evaluate the effects of different cleaning methods
14 on clean surface texture and chemistry of the mesh
15 material."

16 Q. So this would cover a broad scope on how
17 to clean meshes, correct?

18 A. Yes, sir.

19 Q. Doctor, did the protocol for cleaning
20 Ms. Stubblefield's mesh explant use various
21 chemicals?

22 A. Yes.

23 Q. And I believe we talked about those.

24 Sodium hypochlorite, Proteinase K and
25 water, are those the chemicals that were used?

1 A. They used those plus others.

2 Q. Doctor, are those chemicals described in
3 Exhibit 2 to your deposition entitled, "Protocol for
4 Cleaning Surgical Meshes," that was created by
5 Exponent?

6 A. Yes.

7 Q. And was used by Exponent?

8 A. Yes.

9 Q. And, Doctor, did you develop the protocol
10 that was used to clean Ms. Stubblefield's explant?

11 A. Yes.

12 Q. Did Dr. Ong at Exponent use the protocol
13 that you developed?

14 A. Yes.

15 Q. And did he use that protocol to clean
16 Ms. Stubblefield's explant?

17 A. Yes.

18 Q. And was he working under your direction
19 and control?

20 A. Yes.

21 Q. And, Dr. Thames, is the specific protocol
22 used to clean Ms. Stubblefield's explant contained
23 within her case-specific expert report?

24 A. Yes.

25 Q. And is that the specific protocol that we

1 see on page 2?

2 A. Yes.

3 Q. Doctor, if we look at page 5 of your
4 expert report for Ms. Stubblefield, are you there
5 with me?

6 A. Yes, I am.

7 Q. Doctor, there's a blue and white light
8 microscopy photo at the top; is that correct?

9 A. Yes, sir.

10 Q. And, Doctor, you were asked whether your
11 opinions about figure 5 on page 5 were supported by
12 peer-reviewed literature.

13 Do you recall that question?

14 A. Yes, I do.

15 Q. And, Dr. Thames, do you believe, to a
16 reasonable degree of scientific certainty, that the
17 peeling material shown in this figure is proteins?

18 A. Absolutely.

19 Q. And, Dr. Thames, do proteins strongly
20 adhere to medical device products?

21 MR. BOWMAN: Object to form.

22 THE WITNESS: Yes, they do.

23 BY MR. HUTCHINSON:

24 Q. And, Doctor, is that opinion supported in
25 the peer-reviewed literature?

1 A. Absolutely.

2 MR. BOWMAN: Object to form.

3 BY MR. HUTCHINSON:

4 Q. And, Doctor, is what we're seeing here in
5 exhibit -- I'm sorry -- figure 5 on page 5 exactly
6 that?

7 A. Yes, it is.

8 MR. BOWMAN: Object to form.

9 BY MR. HUTCHINSON:

10 Q. Dr. Thames, let's look at page 8 of your
11 expert report.

12 Now, if we look at the yellow line on FTIR
13 spectra on the top, what does the yellow line show?

14 A. It shows that there are proteins present,
15 because it says before cleaning. And the blue fiber
16 is gold or yellow, and it shows that there are
17 proteins present when the cleaning process began,
18 and it shows that there are some 1742, which means
19 decomposition products were present.

20 Q. And, Dr. Thames, what happened to the
21 proteins on Ms. Stubblefield's explant as the
22 cleaning process progressed?

23 MR. BOWMAN: Object to form.

24 THE WITNESS: They were removed. They
25 were cleaned and no longer there, and that's

1 what this progression of FTIR spectra shows.

2 BY MR. HUTCHINSON:

3 Q. And, Doctor, let's look on page 9.

4 We see another FTIR spectra here; is that
5 correct?

6 A. Yes, you do.

7 Q. And I believe I see two blue lines, one
8 red -- I'm sorry. Strike that.

9 I believe I see two lines, one red and one
10 blue; is that right?

11 A. Yes, sir.

12 Q. What does the blue line represent?

13 A. It is the exemplar that's been through the
14 five cleaning steps that we're talking about.

15 Q. And what does the red line represent?

16 A. It's after cleaning blue fiber.

17 Q. And, Doctor, what relationship do these
18 red and blue lines have to each other on the FTIR
19 analysis?

20 A. They are identical.

21 Q. And, Doctor, what does that tell you as a
22 material scientist about whether or not
23 Ms. Stubblefield's mesh oxidized?

24 MR. BOWMAN: Object to form.

25 THE WITNESS: It shows me unequivocally

1 that her mesh did not oxidize.

2 BY MR. HUTCHINSON:

3 Q. Why does it show you that?

4 A. There's no carbonyl frequency showing in
5 this spectra, and certainly it's not an exemplar.

6 MR. HUTCHINSON: I don't have any
7 further questions. Thank you.

8 MR. BOWMAN: I have a couple of
9 follow-ups.

10 FURTHER EXAMINATION

11 BY MR. BOWMAN:

12 Q. With respect to handling of the meshes,
13 did you ever handle any of these meshes for
14 Ms. Stubblefield?

15 A. No.

16 Q. Did you ever perform any kind of --

17 A. I looked at them, but I didn't handle
18 them. I put the tweezer on them, moved them around,
19 but I did not handle them as such.

20 Q. Did you ever perform any kind of tensile
21 testing on these meshes?

22 A. Sir, we didn't have anywhere close to the
23 amount of material to perform a tensile test on it,
24 I mean, not even close.

25 Q. With respect to the explanted sample, were

1 there any tests that you -- I'm sorry.

2 With respect to the explanted sample after
3 it had been run through the cleaning process for the
4 fifth time, did you compare it to the pristine
5 Gynemesh in any other way, other than the FTIR that
6 is represented in figure 11?

7 A. FTIR, SEM and light microscopy.

8 Q. And the SEM and FTIR and light microscopy,
9 were they done -- how were they done?

10 A. Well, light microscopy was done with a
11 light microscope, and the scanning electron
12 microscopy was done with environmental scanning
13 electron microscope.

14 Q. I'll be more clear. Were pictures taken
15 of the entire sample?

16 A. With those devices?

17 Q. With those devices.

18 A. With the light microscope we had pictures
19 taken of them, but that was not the case with SEM.

20 Q. So if there was pitting or if this was
21 cracking or if there was some kind of disturbance on
22 the mesh after it had gone through the five cleaning
23 processes that you determined needed to be done, how
24 would you explain this?

25 A. It would be shown on one or more of these

1 fibers.

2 Q. So even though the FTIR, as you just said
3 a minute ago, is exactly the same as the exemplar
4 Gynemesh, those kinds of defects, how would you
5 explain those?

6 A. Well, if we have oxidation occurring, it
7 shouldn't be unique to a specific site. We should
8 see -- at somewhere along the line of those five
9 explants, we should have seen an occurrence of a
10 peak that never showed up. And it never showed up,
11 and it certainly wasn't there after number five.

12 If it had been present, covered up by a
13 protein or something of that sort, it would not have
14 been washed away. It was never shown up, so it
15 wasn't there.

16 Q. That's what I'm asking you.

17 Did you take SEMs of the entire clean
18 Gynemesh that was taken out of Ms. Stubblefield?

19 A. We took a number of SEMs, and you have
20 those. We only have a few representative spectra
21 here. And we looked it all over, yes, sir.

22 But I can't say that every square
23 centimeter -- no, I'll go better that -- millimeter,
24 because we didn't have much, was looked at and a
25 picture taken.

1 Q. And you'll agree with me that -- well,
2 that mesh hasn't been destroyed, has it?

3 A. No, sir.

4 Q. Now, you'll agree with me that even the
5 FTIR, it's a one-shot analysis; is that right?

6 MR. HUTCHINSON: Object to form.

7 BY MR. BOWMAN:

8 Q. You pick one point and do the FTIR?

9 A. It's a one-shot analysis, but I did it
10 five times.

11 Q. Possibly at five different places,
12 correct?

13 A. Yeah. And, also, we've got SEMs that are
14 certainly more than we have here, and we never saw
15 anything that had a carbonyl band or any pitting or
16 cracking or this explant. And so if there had been
17 any there, I would have found it.

18 Q. Oh, did you go looking for it?

19 A. I did look for it. That's why I did this
20 report, is to find out if it was there, sir.

21 Q. On the final cleaning sample from
22 Ms. Stubblefield, did you go looking for pitting and
23 cracking on the supposedly cleaned, exactly the same
24 as Gynemesh exemplar portion of mesh that you
25 cleaned?

Shelby F. Thames, Ph.D.

1 A. We had nothing to hide with this analyses,
2 and we were looking to see what kind of condition
3 this explant was in. And we have provided for you
4 as reasonable a depiction of the condition of this
5 explant as we can possibly do.

6 MR. BOWMAN: Okay. Thank you. I have
7 no more questions.

8 (CONCLUDED AT 2:31 P.M.)

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1 CERTIFICATE OF COURT REPORTER

2 I, Amy M. Key, CSR, and Notary Public in
3 and for the County of Lamar, State of Mississippi,
4 hereby certify that the foregoing pages, under
5 penalty of perjury, contain a true and correct
6 transcript of the testimony of the witness, as
7 taken by me at the time and place heretofore
8 stated, and later reduced to typewritten form by
9 computer-aided transcription under my supervision
10 and to the best of my skill and ability.

11 I further certify that I placed the witness
12 under oath to truthfully answer the questions in
13 this matter under the power vested in me by the
14 State of Mississippi.

15 I further certify that I am not in the employ
16 of or related to any counsel or party in this
17 matter, and have no interest, monetary or
18 otherwise, in the final outcome of the
19 proceedings.

20 Witness my signature and seal this the
21 _____ day of _____, 2016.

22

23

AMY M. KEY, CSR

24 My Commission Expires June 19, 2016

25

Shelby F. Thames, Ph.D.

1 SIGNATURE OF WITNESS

2

3 I, _____, do solemnly swear that I
 4 have read the foregoing pages and that the same is
 a true and correct transcript of the testimony
 5 given by me at the time and place hereinbefore set
 forth, with the following corrections:

6

PAGE: LINE: SHOULD READ: REASON FOR CHANGE:

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(SIGNATURE)

20

21 Subscribed and sworn

to before me this

22 _____ day of _____, 20____.

23 My commission expires: _____

24

25 Notary Public